

Pilot Study Data Evaluation dated Jan 28, 2002

- A. CO
- B. COHb
- C. Acetonitrile in Blood
- D. 3-ABP Hb Adduct
- E. 4-ABP Hb Adduct
- F. Thromboxane
- G. Prostaglandin
- H. Malondialdehyde in Urine
- I. Creatinine
- J. HDL-Cholesterol
- K. LDL-Cholesterol
- L. Fibrinogen
- M. C-Reactive Protein

Jan Oey

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TABLE 14.1.1-3
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF EXHALATE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL.
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
Carbon Monoxide	(ppm)	Week 1	N	69	68	0.0000
			MEAN, GEO MEAN	24.9, 21.3	5.7, 5.5	
			SD, SE	14.03, 1.69	1.33, 0.16	
			MEDIAN	22.7	5.7	
			MIN, MAX	6.8, 71.4	3.6, 9.6	
			5%, 95%	8.4, 50.4	3.7, 8.1	
		Week 2	N	69	68	0.0000
			MEAN, GEO MEAN	23.8, 20.1	5.2, 4.8	
			SD, SE	14.43, 1.74	1.73, 0.21	
			MEDIAN	21.2	5.2	
			MIN, MAX	4.5, 88.9	0.1, 10.9	
			5%, 95%	6.8, 50.1	3.2, 8.5	
		Week 3	N	68	67	0.0000
			MEAN, GEO MEAN	25.9, 21.6	5.2, 4.9	
			SD, SE	14.90, 1.81	1.63, 0.20	
			MEDIAN	23.7	5.2	
			MIN, MAX	5.3, 65.4	0.3, 10.6	
			5%, 95%	6.3, 55.1	3.2, 8.3	
		Week 6	N	68	67	0.0000
			MEAN, GEO MEAN	26.6, 22.3	6.2, 5.7	
			SD, SE	14.24, 1.73	2.41, 0.29	
			MEDIAN	25.1	5.8	
			MIN, MAX	4.0, 70.5	0.4, 13.8	
			5%, 95%	5.5, 51.1	3.6, 11.6	
		Overall	N	274	270	0.0000
			MEAN, GEO MEAN	25.3, 21.3	5.6, 5.2	
			SD, SE	14.36, 0.87	1.85, 0.11	
			MEDIAN	23.2	5.5	
			MIN, MAX	4.0, 88.9	0.1, 13.8	
			5%, 95%	6.8, 51.2	3.2, 8.8	

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TABLE 14.1.4-3
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF EXHALATE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker	(ppm)	Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value*	Male	Female	P-value*
Carbon Monoxide	Week 1		N	30	39	0.6498	32	36	0.1284
			MEAN, GEO MEAN	23.9, 20.5	25.7, 22.0		5.9, 5.8	5.5, 5.3	
			SD, SE	13.75, 2.51	14.38, 2.30		1.30, 0.23	1.34, 0.22	
			MEDIAN	22.4	22.7		5.9	5.4	
			MIN, MAX	6.8, 71.4	7.8, 66.5		3.6, 9.1	3.7, 9.6	
	Week 2		5%, 95%	7.8, 47.2	8.4, 54.7		3.7, 8.0	4.0, 8.1	
			N	30	39	0.2169	32	36	0.0000
			MEAN, GEO MEAN	20.8, 18.1	26.1, 21.7		6.1, 5.4	4.5, 4.3	
			SD, SE	10.44, 1.91	16.64, 2.66		1.83, 0.32	1.28, 0.21	
			MEDIAN	19.5	22.5		6.0	4.4	
Carbon Monoxide	Week 3		MIN, MAX	4.5, 44.1	6.5, 88.9		0.1, 10.9	2.1, 8.6	
			5%, 95%	6.8, 44.1	6.7, 55.6		4.0, 9.6	2.2, 6.8	
			N	30	38	0.4114	31	36	0.0000
			MEAN, GEO MEAN	24.8, 20.2	26.7, 22.7		6.1, 5.9	4.5, 4.2	
			SD, SE	16.10, 2.94	14.04, 2.28		1.53, 0.28	1.31, 0.22	
	Week 6		MEDIAN	22.7	25.0		6.0	4.5	
			MIN, MAX	5.3, 65.4	5.3, 60.7		3.4, 10.6	0.3, 7.4	
			5%, 95%	6.3, 62.2	7.0, 50.7		4.0, 9.4	3.0, 6.9	
			N	30	38	0.2214	31	36	0.0002
			MEAN, GEO MEAN	24.6, 20.7	28.2, 23.8		7.4, 7.1	5.3, 4.7	

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TABLE 14.1.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
Carboxyhemoglobin (% saturation)	Week 1	N	68	27		
		MEAN, GEO MEAN	4.2, 3.2	0.5, 0.5		
		SD, SE	2.89, 0.35	0.19, 0.04		
		MEDIAN	3.4	0.5		
		MIN, MAX	0.3, 14.8	0.3, 1.0		
	Week 2	5%, 95%	0.9, 8.9	0.3, 0.8		
		N	66	20		0.0000
		MEAN, GEO MEAN	4.1, 3.1	0.5, 0.5		
		SD, SE	2.74, 0.34	0.22, 0.05		
		MEDIAN	3.6	0.5		
	Week 3	MIN, MAX	0.4, 13.3	0.3, 1.1		
		5%, 95%	0.6, 9.1	0.3, 1.0		
		N	67	28		0.0000
		MEAN, GEO MEAN	4.6, 3.6	0.8, 0.6		
		SD, SE	2.99, 0.37	0.68, 0.13		
	Week 6	MEDIAN	3.9	0.5		
		MIN, MAX	0.3, 11.3	0.3, 2.8		
		5%, 95%	0.7, 10.4	0.3, 2.5		
		N	64	33		0.0000
		MEAN, GEO MEAN	4.3, 3.4	0.5, 0.5		
	Overall	SD, SE	2.70, 0.34	0.26, 0.05		
		MEDIAN	4.1	0.5		
		MIN, MAX	0.3, 13.9	0.3, 1.3		
		5%, 95%	0.8, 8.9	0.3, 1.1		
		N	265	108		0.0000
		MEAN, GEO MEAN	4.3, 3.3	0.6, 0.5		
		SD, SE	2.82, 0.17	0.41, 0.04		

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TABLE 14.1.4-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value ^a	Male	Female	P-value ^a
Carboxyhemoglobin (% saturation)	Week 1	N	29	39	0.7329		19	8	0.0118
		MEAN, GEO MEAN	4.0, 3.0	4.3, 3.3			0.6, 0.6	0.4, 0.4	
		SD, SE	2.87, 0.53	2.94, 0.47			0.18, 0.04	0.14, 0.05	
		MEDIAN	3.4	3.4			0.5	0.4	
		MIN, MAX	0.3, 14.8	0.8, 11.4			0.3, 1.0	0.3, 0.7	
	Week 2	5%, 95%	0.4, 7.9	0.9, 11.3			0.3, 1.0	0.3, 0.7	
		N	29	37	0.1442		14	6	0.2922
		MEAN, GEO MEAN	3.5, 2.8	4.5, 3.5			0.6, 0.5	0.4, 0.4	
		SD, SE	2.24, 0.42	3.03, 0.50			0.25, 0.07	0.08, 0.03	
		MEDIAN	3.3	4.7			0.5	0.4	
	Week 3	MIN, MAX	0.4, 8.6	0.4, 13.3			0.3, 1.1	0.3, 0.5	
		5%, 95%	0.5, 8.4	0.6, 10.1			0.3, 1.1	0.3, 0.5	
		N	29	38	0.4552		14	14	0.8158
		MEAN, GEO MEAN	4.4, 3.4	4.8, 3.7			0.7, 0.6	0.8, 0.6	
		SD, SE	3.15, 0.59	2.89, 0.47			0.63, 0.17	0.74, 0.20	
	Week 6	MEDIAN	3.5	4.3			0.5	0.4	
		MIN, MAX	0.6, 11.3	0.3, 9.8			0.3, 2.8	0.3, 2.5	
		5%, 95%	0.7, 11.3	0.5, 9.7			0.3, 2.8	0.3, 2.5	
		N	28	36	0.1961		19	14	0.4040
		MEAN, GEO MEAN	4.0, 3.0	4.6, 3.7			0.6, 0.5	0.5, 0.5	
	Overall	SD, SE	2.81, 0.53	2.61, 0.43			0.25, 0.06	0.29, 0.08	
		MEDIAN	4.0	4.5			0.5	0.4	
		MIN, MAX	0.3, 13.9	0.4, 9.8			0.3, 1.1	0.3, 1.3	
		5%, 95%	0.4, 8.3	0.8, 9.2			0.3, 1.1	0.3, 1.3	
		N	115	150	0.0507		66	42	0.0299
		MEAN, GEO MEAN	4.0, 3.0	4.6, 3.5			0.6, 0.5	0.6, 0.5	
		SD, SE	2.77, 0.26	2.85, 0.23			0.35, 0.04	0.49, 0.07	
		MEDIAN	3.6	4.3			0.5	0.4	
		MIN, MAX	0.3, 14.8	0.3, 13.3			0.3, 2.8	0.3, 2.5	
		5%, 95%	0.5, 10.4	0.8, 9.7			0.3, 1.1	0.3, 1.6	

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TABLE 14.1.1-1
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
Acetonitrile (ng/mL)	Week 1	N	57	52		
		MEAN, GEO MEAN	306.02, 224.95	214.62, 130.14		0.0000
		SD, SE	300.672, 39.825	312.770, 43.373		
		MEDIAN	201.63	100.32		
		MIN, MAX	66.48, 1508.01	33.71, 1521.61		
	Week 2	5%, 95%	80.8, 1004.3	44.4, 972.7		
		N	58	53		0.0010
		MEAN, GEO MEAN	357.86, 260.25	209.85, 151.38		
		SD, SE	326.969, 42.933	180.771, 24.831		
		MEDIAN	265.80	117.58		
Benzene (ppb)	Week 3	MIN, MAX	48.66, 1701.68	32.17, 756.74		
		5%, 95%	78.7, 1003.0	39.2, 664.0		
		N	57	56		0.0006
		MEAN, GEO MEAN	503.17, 299.24	222.63, 163.70		
		SD, SE	639.934, 84.761	205.632, 27.479		
	Week 6	MEDIAN	243.87	135.72		
		MIN, MAX	46.59, 2679.33	42.35, 1168.91		
		5%, 95%	76.5, 2334.0	55.0, 619.9		
		N	57	53		0.0037
		MEAN, GEO MEAN	471.72, 320.42	275.98, 192.48		
Benzene Exhalation (ppb)	Overall	SD, SE	421.643, 55.848	238.629, 32.778		
		MEDIAN	363.52	159.17		
		MIN, MAX	31.69, 1665.36	44.70, 947.37		
		5%, 95%	56.4, 1460.6	62.1, 744.4		
		N	229	214		0.0000
	Overall	MEAN, GEO MEAN	409.47, 273.66	230.73, 158.07		
		SD, SE	446.874, 29.530	238.579, 16.309		
		MEDIAN	242.43	125.55		
		MIN, MAX	31.69, 2679.33	32.17, 1521.61		
		5%, 95%	80.8, 1406.4	47.2, 688.4		

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TABLE I4.1.4-I
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker	(ng/mL)	Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value*	Male	Female	P-value*
Acetonitrile		Week 1	N	18	39	0.0003	24	28	0.2438
			MEAN, GEO MEAN	502.04, 390.23	215.56, 174.45		202.37, 139.86	225.11, 122.34	
			SD, SE	350.343, 82.577	227.415, 36.416		279.883, 57.131	343.226, 64.864	
			MEDIAN	423.35	172.48		113.18	91.43	
			MIN, MAX	132.35, 1346.61	66.48, 1508.01		53.62, 1436.85	33.71, 1521.61	
			5%, 95%	132.4, 1346.6	75.2, 386.2		65.0, 431.1	43.9, 972.7	
		Week 2	N	20	38	0.1182	23	30	0.6344
			MEAN, GEO MEAN	426.13, 324.25	321.94, 231.82		197.48, 158.15	219.34, 146.39	
			SD, SE	349.525, 78.156	313.237, 50.814		144.658, 30.163	206.170, 37.641	
			MEDIAN	335.60	206.97		168.34	112.20	
			MIN, MAX	96.28, 1578.50	48.66, 1701.68		46.04, 688.37	32.17, 756.74	
		Week 3	5%, 95%	99.6, 1195.2	60.9, 1003.0		69.2, 371.9	36.3, 664.0	
			N	19	38	0.0013	24	32	0.0334
			MEAN, GEO MEAN	830.20, 527.59	339.65, 225.36		254.59, 202.98	198.66, 139.32	
			SD, SE	854.396,	426.961, 69.262		174.733, 35.667	225.799, 39.916	
			MEDIAN	429.35	213.44		203.55	114.16	
		Week 6	MIN, MAX	133.94, 2679.33	46.59, 2333.96		54.99, 722.48	42.35, 1168.91	
			5%, 95%	133.9, 2679.3	68.0, 1389.4		59.4, 568.7	44.4, 619.9	
			N	20	37	0.0600	24	29	0.2797
			MEAN, GEO MEAN	488.78, 408.12	462.50, 281.14		241.98, 167.68	304.13, 215.75	
			SD, SE	252.496, 56.460	492.600, 80.983		234.668, 47.901	242.294, 44.993	
			MEDIAN	482.10	254.94		122.41	193.47	
			MIN, MAX	31.69, 1060.80	49.12, 1665.36		52.97, 886.61	44.70, 947.37	
		Overall	5%, 95%	118.7, 1043.6	56.4, 1614.8		66.5, 744.4	62.1, 670.9	
			N	77	152	0.0000	95	119	0.2407
			MEAN, GEO MEAN	559.85, 405.32	333.29, 224.28		224.38, 165.73	235.80, 152.21	
			SD, SE	521.467, 59.427	383.784, 31.129		213.593, 21.914	257.572, 23.612	
			MEDIAN	406.11	194.92		138.68	112.74	
			MIN, MAX	31.69, 2679.33	46.59, 2333.96		46.04, 1436.85	32.17, 1521.61	
			5%, 95%	107.7, 2035.8	75.2, 1389.4		59.4, 688.4	43.9, 756.7	

TABLE 14.1.I-1
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
Acetonitrile (nmol/L)	Week 1	N	57	52		
		MEAN, GEO MEAN	7460.9, 5484.2	5232.3, 3172.7		
		SD, SE	7330.39, 970.93	7625.34, 1057.45		
		MEDIAN	4915.7	2445.8		
		MIN, MAX	1620.8, 36765.3	821.8, 37096.9		
	Week 2	5%, 95%	1969.7, 24485.6	1083.2, 23713.9		
		N	58	53		0.0010
		MEAN, GEO MEAN	8724.8, 6345.0	5116.2, 3690.8		
		SD, SE	7971.50, 1046.71	4407.20, 605.38		
		MEDIAN	6480.1	2866.6		
Acetone (nmol/L)	Week 3	MIN, MAX	1186.3, 41487.0	784.3, 18449.3		
		5%, 95%	1917.7, 24452.2	936.2, 16188.6		
		N	57	56		0.0006
		MEAN, GEO MEAN	12267.3, 7295.4	5427.7, 3991.1		
		SD, SE	15601.59, 2066.48	5013.31, 669.93		
	Week 6	MEDIAN	5945.6	3308.9		
		MIN, MAX	1135.9, 65322.1	1032.5, 28498.0		
		5%, 95%	1864.8, 56901.9	1340.7, 15114.1		
		N	57	53		0.0037
		MEAN, GEO MEAN	11500.5, 7811.8	6728.5, 4692.6		
Acetone (nmol/L)	Overall	SD, SE	10279.67, 1361.58	5817.78, 799.13		
		MEDIAN	8862.6	3880.6		
		MIN, MAX	772.6, 40601.5	1089.8, 23096.9		
		5%, 95%	1376.0, 35608.5	1512.8, 18147.3		
		N	229	214		0.0000
	Overall	MEAN, GEO MEAN	9982.8, 6671.8	5625.2, 3853.7		
		SD, SE	10894.80, 719.95	5816.55, 397.61		
		MEDIAN	5910.4	3060.9		
		MIN, MAX	772.6, 65322.1	784.3, 37096.9		
		5%, 95%	1969.7, 34287.5	1150.7, 16782.5		

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TABLE 14.1.4-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 2 of 7)

Biomarker	(nmol/L)	Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value ^a	Male	Female	P-value ^a
Acetonitrile		Week 1	N	18	39	0.0003	24	28	0.2438
			MEAN, GEO MEAN	12239.6, 9513.7	5255.3, 4253.0		4933.7, 3409.8	5488.2, 2982.7	
			SD, SE	8541.38, 2013.22	5544.38, 887.81		6823.56, 1392.85	8367.85, 1581.38	
			MEDIAN	10321.2	4205.1		2759.2	2229.1	
			MIN, MAX	3226.7, 32830.4	1620.8, 36765.3		1307.3, 35030.4	821.8, 37096.9	
		Week 2	5%, 95%	3226.7, 32830.4	1832.4, 9415.6		1585.4, 10510.9	1070.8, 23713.9	
			N	20	38	0.1182	23	30	0.6344
			MEAN, GEO MEAN	10389.0, 7905.2	7848.8, 5651.7		4814.5, 3855.8	5347.6, 3569.1	
			SD, SE	8521.43, 1905.45	7636.73, 1238.84		3526.75, 735.38	5026.42, 917.69	
			MEDIAN	8181.8	5046.0		4104.1	2735.5	
		Week 3	MIN, MAX	2347.3, 38483.8	1186.3, 41487.0		1122.5, 16782.5	784.3, 18449.3	
			5%, 95%	2427.4, 29140.1	1485.5, 24452.2		1687.1, 9065.9	884.3, 16188.6	
			N	19	38	0.0013	24	32	0.0334
			MEAN, GEO MEAN	20240.3, 12862.6	8280.8, 5494.3		6206.8, 4948.7	4843.4, 3396.6	
			SD, SE	20830.16, 4778.77	10409.32, 1688.61		4260.00, 869.57	5504.96, 973.15	
		Week 6	MEDIAN	10467.6	5203.7		4962.5	2783.2	
			MIN, MAX	3265.5, 65322.1	1135.9, 56901.9		1340.7, 17614.1	1032.5, 28498.0	
			5%, 95%	3265.5, 65322.1	1657.1, 33872.4		1448.9, 13864.7	1082.0, 15114.1	
			N	20	37	0.0600	24	29	0.2797
			MEAN, GEO MEAN	11916.4, 9949.9	11275.7, 6854.3		5899.5, 4088.1	7414.6, 5260.0	
		Overall	SD, SE	6155.86, 1376.49	12009.58, 1974.36		5721.21, 1167.84	5907.12, 1096.92	
			MEDIAN	11753.6	6215.4		2984.2	4716.8	
			MIN, MAX	772.6, 25862.3	1197.5, 40601.5		1291.4, 21615.6	1089.8, 23096.9	
			5%, 95%	2894.8, 25442.0	1376.0, 39367.6		1621.5, 18147.3	1512.8, 16357.0	
			N	77	152	0.0000	95	119	0.2407
			MEAN, GEO MEAN	13649.2, 9881.8	8125.5, 5467.9		5470.5, 4040.4	5748.8, 3710.9	
			SD, SE	12713.35, 1448.82	9356.66, 758.93		5207.41, 534.27	6279.62, 575.65	
			MEDIAN	9901.0	4752.2		3381.0	2748.6	
			MIN, MAX	772.6, 65322.1	1135.9, 56901.9		1122.5, 35030.4	784.3, 37096.9	
			5%, 95%	2626.2, 49631.8	1832.4, 33872.4		1448.9, 16782.5	1070.8, 18449.3	

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TABLE 14.1.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 4 of 7)

Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
Hb adduct of 3-aminobiphenyl ($\mu\text{g/g}$ hemoglobin)	Week 1		N	64	13	
			MEAN, GEO MEAN	3.75, 2.77	0.99, 0.78	
			SD, SE	3.219, 0.402	1.093, 0.303	
			MEDIAN	2.55	0.62	
			MIN, MAX	0.86, 15.03	0.51, 4.59	
	Week 6		5%, 95%	0.9, 10.4	0.5, 4.6	
			N	62	6	0.0290
			MEAN, GEO MEAN	5.08, 3.10	1.52, 1.44	
			SD, SE	8.305, 1.055	0.555, 0.227	
			MEDIAN	2.73	1.40	
Overall			MIN, MAX	0.77, 63.34	1.00, 2.46	
			5%, 95%	1.1, 12.7	1.0, 2.5	
			N	126	19	0.0000
			MEAN, GEO MEAN	4.41, 2.93	1.16, 0.95	
			SD, SE	6.271, 0.559	0.973, 0.223	
			MEDIAN	2.57	0.88	
			MIN, MAX	0.77, 63.34	0.51, 4.59	
			5%, 95%	1.0, 12.3	0.5, 4.6	

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TABLE 14.1.4-1
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
 (Page 4 of 7)

Biomarker		Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value ^a	Male	Female	P-value ^b
Hb adduct of 3-aminobiphenyl (pg/g hemoglobin)	Week 1	N	27	37	0.5184	4	9	0.3159	
			MEAN, GEO MEAN	4.41, 3.05	3.27, 2.58		0.64, 0.62	1.14, 0.86	
			SD, SE	3.978, 0.766	2.479, 0.407		0.175, 0.088	1.301, 0.434	
			MEDIAN	2.74	2.27		0.58	0.72	
			MIN, MAX	0.86, 15.03	0.95, 10.41		0.51, 0.89	0.55, 4.59	
		5%, 95%	0.9, 14.0	1.0, 9.4			0.5, 0.9	0.6, 4.6	
		N	27	35	0.7819	2	4	0.4875	
		MEAN, GEO MEAN	4.34, 3.13	5.65, 3.09		1.91, 1.82	1.33, 1.28		
		SD, SE	3.612, 0.695	10.630, 1.797		0.785, 0.555	0.400, 0.200		
		MEDIAN	2.68	2.78		1.91	1.24		
Overall	Overall	MIN, MAX	0.77, 12.65	0.81, 63.34		1.35, 2.46	1.00, 1.84		
		5%, 95%	1.1, 12.3	1.0, 14.2		1.4, 2.5	1.0, 1.8		
		N	54	72	0.4793	6	13	0.6295	
		MEAN, GEO MEAN	4.38, 3.09	4.43, 2.81		1.06, 0.89	1.20, 0.97		
		SD, SE	3.764, 0.512	7.659, 0.903		0.755, 0.308	1.084, 0.301		
		MEDIAN	2.73	2.29		0.76	0.88		
		MIN, MAX	0.77, 15.03	0.81, 63.34		0.51, 2.46	0.55, 4.59		
		5%, 95%	0.9, 12.7	1.0, 10.4		0.3, 2.5	0.6, 4.6		

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Source: <https://www.industrydocuments.ucsf.edu/docs/ycrj0001>

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TABLE 14.1.1-1
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
Hb adduct of 4-aminobiphenyl (pg/g hemoglobin)	Week 1	N	68	68	68	0.0000
		MEAN, GEO MEAN	34.22, 28.74	7.84, 6.79	4.91, 0.596	
		SD, SE	20.370, 2.495	6.76	6.76	
		MEDIAN	29.84	2.49, 29.69	2.49, 29.69	
		MIN, MAX	5.35, 100.50	3.1, 17.4	3.1, 17.4	
	Week 6	5%, 95%	11.4, 79.9	11.4, 81.7	11.4, 81.7	0.0000
		N	68	67	67	
		MEAN, GEO MEAN	50.52, 35.24	9.31, 8.19	9.31, 8.19	
		SD, SE	95.529, 11.585	5.934, 0.725	5.934, 0.725	
Overall	Week 6	MEDIAN	36.86	7.53	7.53	0.0000
		MIN, MAX	7.27, 808.80	4.09, 40.55	4.09, 40.55	
		5%, 95%	11.4, 81.7	4.4, 20.6	4.4, 20.6	
		N	136	135	135	
		MEAN, GEO MEAN	42.37, 31.82	8.57, 7.45	8.57, 7.45	
	Overall	SD, SE	69.326, 5.945	5.473, 0.471	5.473, 0.471	0.0000
		MEDIAN	32.68	7.12	7.12	
		MIN, MAX	5.35, 808.80	2.49, 40.55	2.49, 40.55	
		5%, 95%	11.4, 81.7	3.4, 20.6	3.4, 20.6	

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TABLE 14.1.4-1
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value ^a	Male	Female	P-value ^b
Hb adduct of 4-aminobiphenyl (pg/g hemoglobin)	Week 1		N	30	38	0.0234	32	36	0.1307
			MEAN, GEO MEAN	42.28, 35.41	27.86, 24.38		7.54, 6.23	8.10, 7.33	
			SD, SE	25.024, 4.569	13.462, 2.184		5.813, 1.028	4.012, 0.669	
			MEDIAN	38.12	26.66		5.50	6.82	
			MIN, MAX	12.37, 100.50	5.35, 67.83		2.90, 29.69	2.49, 23.25	
			5%, 95%	12.8, 90.7	5.4, 50.5		3.1, 23.2	3.0, 17.4	
	Week 6		N	30	38	0.5247	31	36	0.8801
			MEAN, GEO MEAN	38.60, 32.72	59.93, 37.36		9.94, 8.29	8.76, 8.10	
			SD, SE	21.692, 3.960	126.294, 20.488		7.700, 1.383	3.862, 0.644	
			MEDIAN	36.58	37.63		7.50	7.94	
Overall			MIN, MAX	9.56, 97.75	7.27, 808.80	0.2206	4.11, 40.55	4.09, 22.67	0.2096
			5%, 95%	11.4, 74.6	7.3, 90.3		4.3, 27.9	4.4, 15.9	
			N	60	76		63	72	
			MEAN, GEO MEAN	40.44, 34.04	43.90, 30.18		8.72, 7.17	8.43, 7.71	
			SD, SE	23.292, 3.007	90.657, 10.399		6.859, 0.864	3.924, 0.462	
PM3006635371			MEDIAN	36.58	31.50	0.2206	7.06	7.32	0.2096
			MIN, MAX	9.56, 100.50	5.35, 808.80		2.90, 40.55	2.49, 23.25	
			5%, 95%	12.1, 89.0	7.3, 74.9		3.2, 23.2	4.1, 15.9	

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Source: <https://www.industrydocuments.ucsf.edu/docs/yrcj0001>

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
(Page 5 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
11-Dehydrothromboxane B ₂ (pg/mg Creatinin)	Week 1	N	59	55	0.0003
		MEAN, GEO MEAN	985.368, 893.189	705.622, 658.489	
		SD, SE	437.6925, 56.9827	246.5333, 33.2425	
		MEDIAN	931.937	716.848	
		MIN, MAX	345.794, 2284.404	227.688, 1314.159	
		5%, 95%	405.1, 1799.4	267.9, 1150.0	
	Week 2	N	64	56	0.0072
		MEAN, GEO MEAN	1024.565, 924.518	790.034, 731.443	
		SD, SE	471.5304, 58.9413	310.4590, 41.4868	
		MEDIAN	916.502	762.028	
		MIN, MAX	250.508, 2312.883	261.458, 1988.571	
		5%, 95%	457.5, 2121.5	296.0, 1266.4	
	Week 3	N	60	50	0.0031
		MEAN, GEO MEAN	1059.358, 955.688	805.378, 759.735	
		SD, SE	487.2286, 62.9009	232.4852, 35.7068	
		MEDIAN	1001.278	762.784	
		MIN, MAX	333.333, 2422.550	203.209, 1393.314	
		5%, 95%	394.6, 2078.3	436.9, 1266.3	
	Overall	N	183	161	0.0000
		MEAN, GEO MEAN	1023.335, 924.293	765.963, 714.021	
		SD, SE	464.6157, 34.3454	274.0584, 21.5988	
		MEDIAN	929.912	756.454	
		MIN, MAX	250.508, 2422.550	203.209, 1988.571	
		5%, 95%	416.1, 1962.0	296.0, 1239.7	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
11-Dihydrothromboxane B ₂ (pmol/mg Creatin)	Week 1	N	59	55	0.0003
		MEAN, GEO MEAN	2.670, 2.421	1.912, 1.784	
		SD, SE	1.1862, 0.1544	0.6681, 0.0901	
		MEDIAN	2.526	1.943	
		MIN, MAX	0.937, 6.191	0.617, 3.561	
	Week 2	5%, 95%	1.1, 4.9	0.7, 3.1	0.0072
		N	64	56	
		MEAN, GEO MEAN	2.777, 2.505	2.141, 1.982	
		SD, SE	1.2778, 0.1597	0.8413, 0.1124	
		MEDIAN	2.484	2.065	
11-Dihydrothromboxane B ₂ (pmol/mg Creatin)	Week 3	MIN, MAX	0.679, 6.268	0.709, 5.389	0.0031
		5%, 95%	1.2, 5.7	0.8, 3.4	
		N	60	50	
		MEAN, GEO MEAN	2.871, 2.590	2.183, 2.059	
		SD, SE	1.3204, 0.1705	0.6842, 0.0968	
	Overall	MEDIAN	2.714	2.067	0.0000
		MIN, MAX	0.903, 6.565	0.551, 3.776	
		5%, 95%	1.1, 5.6	1.2, 3.4	
		N	183	161	
		MEAN, GEO MEAN	2.773, 2.505	2.076, 1.935	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
11-Dehydrothromboxane B ₂ (pg/mL)	Week 1	N	59	55	0.1639
		MEAN, GEO MEAN	844.5, 687.0	672.7, 573.2	
		SD, SE	658.82, 85.77	397.87, 53.65	
		MEDIAN	684.0	594.0	
		MIN, MAX	222.0, 3636.0	246.0, 1758.0	
		5%, 95%	243.0, 2281.0	248.0, 1572.0	
	Week 2	N	64	56	0.0545
		MEAN, GEO MEAN	1011.7, 809.2	817.9, 647.5	
		SD, SE	708.09, 88.51	691.63, 92.42	
		MEDIAN	775.5	646.0	
		MIN, MAX	222.0, 3362.0	228.0, 4070.0	
		5%, 95%	271.0, 2717.0	260.0, 2036.0	
	Week 3	N	60	50	0.2053
		MEAN, GEO MEAN	869.5, 735.1	740.0, 633.7	
		SD, SE	541.28, 69.88	423.67, 59.92	
		MEDIAN	693.0	634.0	
		MIN, MAX	236.0, 2876.0	228.0, 1904.0	
		5%, 95%	264.5, 1978.5	262.0, 1567.0	
	Overall	N	183	161	0.0067
		MEAN, GEO MEAN	911.1, 743.8	744.1, 617.0	
		SD, SE	642.20, 47.47	525.82, 41.44	
		MEDIAN	720.0	603.0	
		MIN, MAX	222.0, 3636.0	228.0, 4070.0	
		5%, 95%	256.0, 2168.0	256.0, 1600.0	

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TABLE 14.2.I-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
11-Dihydrothromboxane B ₂ (pmol/L)	Week 1	N	59	55	
		MEAN, GEO MEAN	2288.5, 1861.8	1823.0, 1553.4	
		SD, SE	1785.40, 232.44	1078.22, 145.39	
		MEDIAN	1853.6	1609.7	
		MIN, MAX	601.6, 9853.6	666.7, 4764.2	
		5%, 95%	658.5, 6181.5	672.1, 4260.1	
	Week 2	N	64	56	
		MEAN, GEO MEAN	2741.6, 2193.0	2216.5, 1754.9	
		SD, SE	1918.92, 239.86	1874.30, 250.46	
		MEDIAN	2101.6	1750.7	
		MIN, MAX	601.6, 9111.0	617.9, 11029.7	
		5%, 95%	734.4, 7363.1	704.6, 5517.6	
	Week 3	N	60	50	
		MEAN, GEO MEAN	2356.2, 1992.0	2005.3, 1717.4	
		SD, SE	1466.87, 189.37	1148.15, 162.37	
		MEDIAN	1878.0	1718.2	
		MIN, MAX	639.6, 7794.0	617.9, 5159.8	
		5%, 95%	716.8, 5361.8	710.0, 4246.6	
	Overall	N	183	161	
		MEAN, GEO MEAN	2469.2, 2015.7	2016.5, 1672.0	
		SD, SE	1740.37, 128.65	1424.98, 112.30	
		MEDIAN	1951.2	1634.1	
		MIN, MAX	601.6, 9853.6	617.9, 11029.7	
		5%, 95%	693.8, 5875.3	693.8, 4336.0	

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TABLE I4.2.1-2
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
11-Dihydrothromboxane B ₂ (pg/24hr)	Week 1	N	59	55	0.0064
		MEAN, GEO MEAN	1357797.915, 1184665.613	1007599.000, 934075.235	
		SD, SE	730785.0879, 95140.1147	389305.9122, 52493.9985	
		MEDIAN	1308300.000	934150.000	
		MIN, MAX	393240.000, 4272300.000	438200.000, 2065650.000	
		5%, 95%	448200.0, 2908320.0	482400.0, 1782000.0	
	Week 2	N	64	56	0.0918
		MEAN, GEO MEAN	1386884.844, 1229501.044	1159310.268, 1046352.127	
		SD, SE	682544.6144, 85318.0768	584007.4679, 78041.2806	
		MEDIAN	1213220.000	1120780.000	
		MIN, MAX	388500.000, 3025800.000	382800.000, 3993300.000	
	Week 3	5%, 95%	530660.0, 2841768.0	465365.0, 2037840.0	
		N	60	50	0.1937
		MEAN, GEO MEAN	1587630.817, 1315000.013	1236106.050, 1142519.707	
		SD, SE	1227749.8372, 158501.8224	479263.3232, 67778.0692	
		MEDIAN	1274000.000	1237080.000	
	Overall	MIN, MAX	379376.000, 8904654.000	367080.000, 2522260.000	
		5%, 95%	480220.0, 2839780.0	539110.0, 2000300.0	
		N	183	161	0.0007
		MEAN, GEO MEAN	1443325.443, 1241938.965	1131333.052, 1034419.394	
		SD, SE	911296.7973, 67364.9977	497697.7132, 39224.0747	
		MEDIAN	1272642.000	1083560.000	
		MIN, MAX	379376.000, 8904654.000	367080.000, 3993300.000	
		5%, 95%	476580.0, 2841768.0	472650.0, 1926400.0	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
(Page 4 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
11-Dihydrothromboxane B ₂ (pmol/24hr)	Week 1	N	59	55	0.0064
		MEAN, GEO MEAN	3679.632, 3210.444	2730.593, 2531.344	
		SD, SE	1980.4276, 257.8297	1055.0191, 142.2587	
		MEDIAN	3545.493	2531.547	
		MIN, MAX	1065.680, 11577.933	1187.522, 5597.912	
		5%, 95%	1214.6, 7881.5	1307.3, 4829.2	
	Week 2	N	64	56	0.0918
		MEAN, GEO MEAN	3758.458, 3331.948	3141.731, 2835.616	
		SD, SE	1849.6959, 231.2120	1582.6602, 211.4919	
		MEDIAN	3287.826	3037.314	
		MIN, MAX	1052.835, 8199.918	1037.388, 10821.843	
		5%, 95%	1438.1, 7701.2	1261.1, 5522.5	
	Week 3	N	60	50	0.1937
		MEAN, GEO MEAN	4302.480, 3563.650	3349.847, 3096.228	
		SD, SE	3327.2020, 429.5399	1298.8037, 183.6786	
		MEDIAN	3452.540	3352.487	
		MIN, MAX	1028.109, 24131.612	994.787, 6835.325	
		5%, 95%	1301.4, 7695.8	1461.0, 5420.8	
	Overall	N	183	161	0.0007
		MEAN, GEO MEAN	3911.412, 3365.655	3065.913, 2803.277	
		SD, SE	2469.6143, 182.5591	1348.7608, 106.2972	
		MEDIAN	3448.860	2936.448	
		MIN, MAX	1028.109, 24131.612	994.787, 10821.843	
		5%, 95%	1291.5, 7701.2	1280.9, 5220.5	

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Source: <https://www.industrydocuments.ucsf.edu/docs/ycrj0001>

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
8-epi-prostaglandin F _{2α} (pg/mg Creatinin)	Week 1	N	65	63	0.0000
		MEAN, GEO MEAN	1850.916, 1672.752	1100.820, 1046.146	
		SD, SE	876.8792, 108.7635	345.5869, 43.5399	
		MEDIAN	1711.133	1059.006	
		MIN, MAX	628.533, 5774.566	337.011, 2047.308	
		5%, 95%	741.2, 3277.1	634.1, 1828.8	
	Week 2	N	69	67	0.0000
		MEAN, GEO MEAN	2006.274, 1774.855	1172.227, 1115.110	
		SD, SE	1089.3046, 131.1369	387.4002, 47.3285	
		MEDIAN	1581.213	1098.068	
		MIN, MAX	649.573, 6076.687	421.429, 2750.000	
	Week 3	5%, 95%	854.9, 4021.2	715.2, 1814.7	
		N	66	61	0.0000
		MEAN, GEO MEAN	1919.242, 1759.908	1145.211, 1084.428	
		SD, SE	819.5982, 100.8856	374.0712, 47.8949	
		MEDIAN	1732.134	1102.506	
	Overall	MIN, MAX	675.556, 4511.384	514.825, 1950.000	
		5%, 95%	836.2, 3592.3	629.4, 1725.5	
		N	200	191	0.0000
		MEAN, GEO MEAN	1927.062, 1736.153	1140.046, 1082.188	
		SD, SE	936.0869, 66.1913	369.0214, 26.7015	
		MEDIAN	1710.627	1088.452	
		MIN, MAX	628.533, 6076.687	337.011, 2750.000	
		5%, 95%	813.5, 3650.9	642.5, 1808.2	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
8-epi-prostaglandin F _{2α} (pmol/mg Creatin)	Week 1	N	65	63	0.0000
		MEAN, GEO MEAN	5.220, 4.717	3.104, 2.950	
		SD, SE	2.4728, 0.3067	0.9746, 0.1228	
		MEDIAN	4.825	2.986	
		MIN, MAX	1.772, 16.284	0.950, 5.773	
		5%, 95%	2.1, 9.2	1.8, 5.2	
	Week 2	N	69	67	0.0000
		MEAN, GEO MEAN	5.658, 5.005	3.306, 3.145	
		SD, SE	3.0719, 0.3698	1.0924, 0.1335	
		MEDIAN	4.459	3.097	
		MIN, MAX	1.832, 17.136	1.188, 7.755	
		5%, 95%	2.4, 11.3	2.0, 5.1	
	Week 3	N	66	61	0.0000
		MEAN, GEO MEAN	5.412, 4.963	3.229, 3.058	
		SD, SE	2.3112, 0.2845	1.0549, 0.1351	
		MEDIAN	4.885	3.109	
		MIN, MAX	1.905, 12.722	1.452, 5.499	
		5%, 95%	2.4, 10.1	1.8, 4.9	
	Overall	N	200	191	0.0000
		MEAN, GEO MEAN	5.434, 4.896	3.215, 3.052	
		SD, SE	2.6398, 0.1867	1.0406, 0.0753	
		MEDIAN	4.824	3.069	
		MIN, MAX	1.772, 17.136	0.950, 7.755	
		5%, 95%	2.3, 10.3	1.8, 5.1	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
8-epi-prostaglandin F _{2α} (pg/mL)	Week 1	N	65	63	0.0083
		MEAN, GEO MEAN	1605.1, 1208.4	1020.2, 846.1	
		SD, SE	1340.18, 166.23	696.70, 87.78	
		MEDIAN	1064.0	769.0	
		MIN, MAX	316.0, 5950.0	280.0, 3363.0	
	Week 2	5%, 95%	397.0, 5050.0	359.0, 2638.0	
		N	69	67	0.0001
		MEAN, GEO MEAN	1910.4, 1472.5	1110.4, 883.0	
		SD, SE	1398.10, 168.31	784.68, 95.86	
		MEDIAN	1616.0	739.0	
8-epi-prostaglandin F _{2α} (pg/mL)	Week 3	MIN, MAX	359.0, 7271.0	270.0, 3297.0	0.0001
		5%, 95%	417.0, 3983.0	344.0, 2791.0	
		N	66	61	
		MEAN, GEO MEAN	1546.1, 1270.4	975.2, 818.3	
		SD, SE	1045.25, 128.66	651.06, 83.36	
	Overall	MEDIAN	1187.0	757.0	0.0000
		MIN, MAX	349.0, 4779.0	275.0, 3143.0	
		5%, 95%	463.0, 3938.0	390.0, 2422.0	
		N	200	191	
		MEAN, GEO MEAN	1691.0, 1315.2	1037.5, 849.7	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
8-epi-prostaglandin F _{2α} (pmol/L)	Week 1	N	65	63	0.0083
		MEAN, GEO MEAN	4526.5, 3407.6	2876.9, 2385.9	
		SD, SE	3779.29, 468.76	1964.71, 247.53	
		MEDIAN	3000.5	2168.6	
		MIN, MAX	891.1, 16779.0	789.6, 9483.7	
		5%, 95%	1119.5, 14241.0	1012.4, 7439.2	
	Week 2	N	69	67	0.0001
		MEAN, GEO MEAN	5387.5, 4152.6	3131.2, 2490.2	
		SD, SE	3942.64, 474.64	2212.78, 270.33	
		MEDIAN	4557.1	2084.0	
		MIN, MAX	1012.4, 20504.2	761.4, 9297.5	
		5%, 95%	1175.9, 11232.1	970.1, 7870.6	
	Week 3	N	66	61	0.0001
		MEAN, GEO MEAN	4360.1, 3582.4	2750.1, 2307.5	
		SD, SE	2947.60, 362.82	1835.99, 235.07	
		MEDIAN	3347.4	2134.7	
		MIN, MAX	984.2, 13476.8	775.5, 8863.3	
		5%, 95%	1305.7, 11105.2	1099.8, 6830.0	
	Overall	N	200	191	0.0000
		MEAN, GEO MEAN	4768.6, 3708.9	2925.6, 2396.3	
		SD, SE	3598.67, 254.46	2012.59, 145.63	
		MEDIAN	3405.2	2151.7	
		MIN, MAX	891.1, 20504.2	761.4, 9483.7	
		5%, 95%	1164.7, 11700.2	1012.4, 7439.2	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
8-epi-prostaglandin F _{2α} (pg/24hr)	Week 1	N	65	63	0.0000
		MEAN, GEO MEAN	250239.615, 2134883.086	1599335.921, 1448451.638	
		SD, SE	1374713.9941, 170512.2854	746231.0968, 94016.2811	
		MEDIAN	2268160.000	1470600.000	
		MIN, MAX	345390.000, 6602325.000	403200.000, 4204250.000	
		5%, 95%	720510.0, 4646400.0	693220.0, 3129140.0	
	Week 2	N	69	67	0.0000
		MEAN, GEO MEAN	2615423.536, 2305044.057	1677899.179, 1531280.985	
		SD, SE	1321662.0149, 159109.4092	775489.7293, 94741.1493	
		MEDIAN	2333120.000	1430580.000	
		MIN, MAX	702900.000, 7718500.000	499730.000, 4601300.000	
	Week 3	5%, 95%	855000.0, 4944280.0	879360.0, 3133645.0	
		N	66	61	0.0000
		MEAN, GEO MEAN	2960816.576, 2349204.304	1699148.148, 1532621.565	
		SD, SE	2992871.4272, 368397.0063	810596.3382, 103786.2260	
		MEDIAN	2527070.000	1484400.000	
	Overall	MIN, MAX	567750.000, 24022683.000	580650.000, 3757600.000	
		5%, 95%	728420.0, 5346600.0	754725.0, 3443440.0	
		N	200	191	0.0000
		MEAN, GEO MEAN	2692647.715, 2262428.046	1658771.963, 1503869.889	
		SD, SE	2041610.8409, 144363.6870	774553.3047, 56044.7102	
		MEDIAN	2346100.000	1445840.000	
		MIN, MAX	345390.000, 24022683.000	403200.000, 4601300.000	
		5%, 95%	732310.0, 5162100.0	775520.0, 3270240.0	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
8-epi-prostaglandin F _{2α} (pmol/24hr)	Week 1	N	65	63	0.0000
		MEAN, GEO MEAN	7056.570, 6020.370	4510.127, 4084.634	
		SD, SE	3876.6935, 480.8446	2104.3717, 265.1259	
		MEDIAN	6396.211	4147.092	
		MIN, MAX	974.000, 18618.557	1137.024, 11855.985	
		5%, 95%	2031.8, 13102.8	1954.9, 8824.2	
	Week 2	N	69	67	0.0000
		MEAN, GEO MEAN	7375.494, 6500.224	4731.676, 4318.212	
		SD, SE	3727.0869, 448.6885	2186.8810, 267.1700	
		MEDIAN	6579.398	4034.236	
		MIN, MAX	1982.178, 21766.170	1409.239, 12975.666	
		5%, 95%	2411.1, 13942.9	2479.8, 8836.9	
	Week 3	N	66	61	0.0000
		MEAN, GEO MEAN	8349.503, 6624.756	4791.598, 4321.993	
		SD, SE	8439.8974, 1038.8796	2285.8817, 292.6772	
		MEDIAN	7126.338	4186.008	
		MIN, MAX	1601.055, 67743.966	1637.433, 10596.432	
		5%, 95%	2054.1, 15077.4	2128.3, 9710.5	
	Overall	N	200	191	0.0000
		MEAN, GEO MEAN	7593.267, 6380.047	4677.737, 4240.913	
		SD, SE	5757.3426, 407.1056	2184.2403, 158.0461	
		MEDIAN	6616.002	4077.269	
		MIN, MAX	974.000, 67743.966	1137.024, 12975.666	
		5%, 95%	2065.1, 14557.1	2187.0, 9222.1	

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Source: <https://www.industrydocuments.ucsf.edu/docs/ycrj0001>

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value*
Malondialdehyde (umol/mg Creatin)	Week 1	N		67	68	
		MEAN, GEO MEAN		0.002, 0.002	0.002, 0.002	
		SD, SE		0.0011, 0.0001	0.0012, 0.0001	
		MEDIAN		0.002	0.001	
		MIN, MAX		0.001, 0.006	0.001, 0.009	
		5%, 95%		0.0, 0.0	0.0, 0.0	
	Week 2	N		68	67	
		MEAN, GEO MEAN		0.002, 0.001	0.002, 0.002	
		SD, SE		0.0007, 0.0001	0.0008, 0.0001	
		MEDIAN		0.002	0.002	
		MIN, MAX		0.001, 0.004	0.001, 0.004	
	Week 3	N		67	67	
		MEAN, GEO MEAN		0.002, 0.002	0.002, 0.001	
		SD, SE		0.0008, 0.0001	0.0009, 0.0001	
		MEDIAN		0.002	0.001	
		MIN, MAX		0.001, 0.006	0.001, 0.006	
	Overall	N		202	202	
		MEAN, GEO MEAN		0.002, 0.002	0.002, 0.002	
		SD, SE		0.0009, 0.0001	0.0010, 0.0001	
		MEDIAN		0.002	0.002	
		MIN, MAX		0.001, 0.006	0.001, 0.009	
		5%, 95%		0.0, 0.0	0.0, 0.0	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
Malondialdehyde ($\mu\text{mol}/24\text{hr}$)	Week 1	N	67	68	68	0.9649
		MEAN, GEO MEAN	2,490, 2,181	2,478, 2,244	2,478, 2,244	
		SD, SE	1,4134, 0,1727	1,5208, 0,1844	1,5208, 0,1844	
		MEDIAN	2,139	2,263	2,263	
		MIN, MAX	0,444, 8,554	1,220, 12,527	1,220, 12,527	
		5%, 95%	1,0, 4,9	1,3, 4,5	1,3, 4,5	
	Week 2	N	68	67	67	0.7816
		MEAN, GEO MEAN	2,255, 2,113	2,447, 2,255	2,447, 2,255	
		SD, SE	0,8269, 0,1003	1,0949, 0,1338	1,0949, 0,1338	
		MEDIAN	2,202	2,030	2,030	
		MIN, MAX	0,756, 5,132	1,152, 6,535	1,152, 6,535	
		5%, 95%	1,2, 3,8	1,4, 4,7	1,4, 4,7	
	Week 3	N	67	67	67	0.6531
		MEAN, GEO MEAN	2,552, 2,124	2,317, 2,092	2,317, 2,092	
		SD, SE	2,0332, 0,2484	1,2997, 0,1588	1,2997, 0,1588	
		MEDIAN	2,116	1,959	1,959	
		MIN, MAX	0,383, 14,912	0,794, 9,953	0,794, 9,953	
		5%, 95%	0,8, 6,5	1,2, 4,3	1,2, 4,3	
	Overall	N	202	202	202	0.9806
		MEAN, GEO MEAN	2,432, 2,139	2,414, 2,196	2,414, 2,196	
		SD, SE	1,5026, 0,1057	1,3131, 0,0924	1,3131, 0,0924	
		MEDIAN	2,159	2,078	2,078	
		MIN, MAX	0,383, 14,912	0,794, 12,527	0,794, 12,527	
		5%, 95%	1,0, 4,8	1,3, 4,4	1,3, 4,4	

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
Malondialdehyde ($\mu\text{mol/L}$)	Week 1	N	67	68		
		MEAN, GEO MEAN	1.54, 1.27	1.60, 1.37		
		SD, SE	1.106, 0.135	0.974, 0.118		
		MEDIAN	1.18	1.21		
		MIN, MAX	0.40, 6.11	0.48, 5.35		
	Week 2	5%, 95%	0.5, 4.0	0.6, 3.7		
		N	68	67		0.6346
		MEAN, GEO MEAN	1.58, 1.35	1.50, 1.30		
		SD, SE	0.887, 0.108	0.834, 0.102		
		MEDIAN	1.38	1.29		
Overall	Week 3	MIN, MAX	0.41, 4.31	0.49, 3.89		
		5%, 95%	0.6, 3.6	0.6, 3.2		
		N	67	67		0.3794
		MEAN, GEO MEAN	1.38, 1.19	1.32, 1.12		
		SD, SE	0.898, 0.110	0.890, 0.109		
	Overall	MEDIAN	1.20	1.11		
		MIN, MAX	0.40, 6.30	0.40, 6.26		
		5%, 95%	0.5, 2.8	0.5, 2.5		
		N	202	202		0.8459
		MEAN, GEO MEAN	1.50, 1.27	1.47, 1.26		

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Source: <https://www.industrydocuments.ucsf.edu/docs/yrcj0001>

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TABLE 14.2.1-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
24-hr Urine Creatinine (mg/24hr)	Week 1		N	69	68	0.2965
			MEAN, GEO MEAN	1377.160, 1270.735	1478.498, 1402.911	
			SD, SE	519.1772, 62.5016	483.0673, 58.5805	
			MEDIAN	1378.980	1359.550	
			MIN, MAX	332.160, 3002.125	500.800, 2973.880	
	Week 2		5%, 95%	614.8, 2205.0	845.6, 2386.0	
			N	69	68	0.4656
			MEAN, GEO MEAN	1372.680, 1298.723	1434.754, 1363.027	
			SD, SE	457.4009, 55.0646	469.6448, 56.9528	
			MEDIAN	1316.480	1385.170	
24-hr Urine Creatinine (mg/24hr)	Week 3		MIN, MAX	505.300, 2577.710	735.150, 2728.350	0.2684
			5%, 95%	726.3, 2201.8	803.7, 2238.5	
			N	68	67	
			MEAN, GEO MEAN	1572.331, 1320.802	1502.281, 1396.406	
			SD, SE	1665.3258, 201.9504	567.5461, 69.3368	
	Overall		MEDIAN	1341.625	1396.050	0.0862
			MIN, MAX	379.500, 14230.404	410.000, 3032.400	
			5%, 95%	586.3, 2331.0	715.4, 2760.6	
			N	206	203	
			MEAN, GEO MEAN	1440.085, 1296.475	1471.694, 1387.293	

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Source: <https://www.industrydocuments.ucsf.edu/docs/yrcj0001>

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TABLE 14.2.1-1
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL.
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value ^a
HDL-Cholesterol (mg/dL)	Week 1	N		69	68	
		MEAN, GEO MEAN		47, 45	55, 53	
		SD, SE		11.1, 1.3	14.8, 1.8	
		MEDIAN		46	53	
		MIN, MAX		23, 81	26, 96	
	Week 3	5%, 95%		30.0, 62.0	34.0, 79.0	
		N		68	67	
		MEAN, GEO MEAN		46, 45	54, 52	
		SD, SE		12.0, 1.5	13.6, 1.7	
		MEDIAN		44	52	
Overall	Week 6	MIN, MAX		24, 79	31, 86	
		5%, 95%		31.0, 64.0	33.0, 81.0	
		N		68	67	
		MEAN, GEO MEAN		45, 44	54, 52	
		SD, SE		10.1, 1.2	13.0, 1.6	
	Overall	MEDIAN		46	54	
		MIN, MAX		28, 82	29, 89	
		5%, 95%		30.0, 61.0	37.0, 78.0	
		N		205	202	
		MEAN, GEO MEAN		46, 45	54, 53	

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TABLE 14.2.3-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
(Page 1 of ?)

Biomarker	(mg/dL)	Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value*	Male	Female	P-value*
IDL-Cholesterol		Week 1	N	30	39	0.2098	32	36	0.0001
			MEAN, GEO MEAN	45, 44	48, 46		47, 46	61, 60	
			SD, SE	9.8, 1.8	12.0, 1.9		12.1, 2.1	14.0, 2.3	
			MEDIAN	44	50		46	60	
			MIN, MAX	30, 62	23, 81		26, 77	36, 96	
			5%, 95%	30.0, 62.0	29.0, 62.0		27.0, 66.0	41.0, 92.0	
		Week 3	N	30	38	0.1921	31	36	0.0001
			MEAN, GEO MEAN	44, 43	48, 46		47, 46	60, 59	
			SD, SE	10.0, 1.8	13.3, 2.2		11.6, 2.1	12.2, 2.0	
			MEDIAN	44	48		45	58	
			MIN, MAX	31, 63	24, 79		31, 77	40, 86	
			5%, 95%	31.0, 63.0	25.0, 75.0		32.0, 73.0	40.0, 85.0	
		Week 6	N	30	38	0.2006	31	36	0.0001
			MEAN, GEO MEAN	44, 43	47, 45		47, 46	60, 59	
			SD, SE	9.0, 1.6	10.9, 1.8		11.1, 2.0	11.9, 2.0	
			MEDIAN	43	47		44	57	
			MIN, MAX	30, 65	28, 82		29, 74	41, 89	
			5%, 95%	31.0, 61.0	29.0, 61.0		33.0, 71.0	45.0, 81.0	
		Overall	N	90	115	0.0346	94	108	0.0000
			MEAN, GEO MEAN	44, 43	48, 46		47, 46	60, 59	
			SD, SE	9.5, 1.0	12.0, 1.1		11.5, 1.2	12.6, 1.2	
			MEDIAN	44	47		45	58	
			MIN, MAX	30, 65	23, 82		26, 77	36, 96	
			5%, 95%	31.0, 62.0	29.0, 64.0		32.0, 71.0	43.0, 85.0	

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Source: <https://www.industrydocuments.ucsf.edu/docs/ycrj0001>

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TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
(Page 2 of 2)

Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value*
LDL-Cholesterol (mg/dL)	Week 1	N	67	66	66	0.0532
		MEAN, GEO MEAN	121, 117	112, 108	112, 108	
		SD, SE	31.7, 3.9	29.6, 3.6	29.6, 3.6	
		MEDIAN	121	109	109	
		MIN, MAX	55, 231	56, 200	56, 200	
	Week 3	5%, 95%	76.0, 172.0	75.0, 173.0	75.0, 173.0	
		N	67	67	67	0.0457
		MEAN, GEO MEAN	116, 113	106, 102	106, 102	
		SD, SE	28.5, 3.5	30.6, 3.7	30.6, 3.7	
		MEDIAN	119	100	100	
Cholesterol (mg/dL)	Week 6	MIN, MAX	60, 199	36, 190	36, 190	
		5%, 95%	69.0, 164.0	60.0, 153.0	60.0, 153.0	
		N	68	67	67	0.1972
		MEAN, GEO MEAN	118, 114	111, 106	111, 106	
		SD, SE	32.0, 3.9	34.4, 4.2	34.4, 4.2	
	Overall	MEDIAN	120	109	109	
		MIN, MAX	50, 227	29, 214	29, 214	
		5%, 95%	73.0, 163.0	61.0, 168.0	61.0, 168.0	
		N	202	200	200	0.0025
		MEAN, GEO MEAN	119, 115	110, 105	110, 105	

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TABLE 14.2.3-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
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Biomarker	(mg/dL)	Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value ^a	Male	Female	P-value ^a
LDL-Cholesterol		Week 1	N	29	38	0.5226	30	36	0.2463
			MEAN, GEO MEAN	123, 118	120, 116		107, 104	116, 112	
			SD, SE	30.5, 5.7	32.9, 5.3		28.0, 5.1	30.8, 5.1	
			MEDIAN	122	121		101	112	
			MIN, MAX	55, 175	57, 231		56, 173	56, 200	
		Week 3	5%, 95%	61.0, 170.0	76.0, 181.0		62.0, 157.0	75.0, 185.0	
			N	30	37	0.0898	31	36	0.1908
			MEAN, GEO MEAN	122, 119	112, 108		102, 96	110, 107	
			SD, SE	27.5, 5.0	29.0, 4.8		35.1, 6.3	26.0, 4.3	
			MEDIAN	124	109		97	113	
		Week 6	MIN, MAX	66, 174	60, 199		36, 190	60, 164	
			5%, 95%	72.0, 164.0	64.0, 173.0		55.0, 170.0	62.0, 153.0	
			N	30	38	0.4043	31	36	0.6017
			MEAN, GEO MEAN	120, 116	117, 113		109, 101	114, 110	
			SD, SE	30.4, 5.5	33.6, 5.5		38.8, 7.0	30.5, 5.1	
		Overall	MEDIAN	124	114		109	108	
			MIN, MAX	58, 187	50, 227		29, 214	64, 185	
			5%, 95%	73.0, 163.0	73.0, 185.0		52.0, 165.0	72.0, 185.0	
			N	89	113	0.0781	92	108	0.0884
			MEAN, GEO MEAN	121, 118	116, 112		106, 100	113, 109	

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Source: <https://www.industrydocuments.ucsf.edu/docs/yrcj0001>

TABLE 11-1 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
 (Page 3 of 7)

Fibrinogen	(mg/dL)	Week 1		Week 3		Week 6		Overall		
		Timepoint	Statistic	Smokers	Non-Smokers	P-Value	N	MEAN, GEO MEAN	SD, SE	MIN, MAX
Fibrinogen	0.0006	299, 292	69	68	69	0.0003	67	290, 277	91.7, 11.2	79.3, 9.7
		SD, SE	72.5, 8.7	72.4, 8.8	72.5, 8.7		67	280, 269	90.1, 7.9	63.1, 7.8
		MEAN, GEO MEAN	290, 277	282, 240	280, 269		66	280, 265	80.1, 7.9	63.1, 7.8
		N	67	67	66		65	280, 265	80.1, 7.9	63.1, 7.8
		Week 3								
		SD, SE	91.7, 11.2	79.3, 9.7	79.3, 9.7			121.64	123, 394	123, 394
		MEAN, GEO MEAN	290, 277	282, 240	280, 269			121.64	123, 394	123, 394
		N	67	67	66			121.64	123, 394	123, 394
		Week 6						121.64	123, 394	123, 394
		SD, SE	90.1, 7.9	63.1, 7.8	63.1, 7.8			121.64	123, 394	123, 394
		MEAN, GEO MEAN	280, 265	280, 265	280, 269			121.64	123, 394	123, 394
		N	65	65	66			121.64	123, 394	123, 394
		Overall						146.0, 354.0	146.0, 354.0	146.0, 354.0
		SD, SE	80.1, 7.9	63.1, 7.8	63.1, 7.8			146.0, 354.0	146.0, 354.0	146.0, 354.0
		MEAN, GEO MEAN	280, 265	280, 265	280, 269			146.0, 354.0	146.0, 354.0	146.0, 354.0
		N	65	65	66			146.0, 354.0	146.0, 354.0	146.0, 354.0

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TABLE 14.2.3-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
(Page 3 of 7)

Biomarker	(mg/dL)	Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value*	Male	Female	P-value*
Fibrinogen	Week 1		N	30	39	0.0000	32	36	0.0037
			MEAN, GEO MEAN	261, 257	329, 322		229, 223	282, 271	
			SD, SE	47.9, 8.7	75.1, 12.0		53.2, 9.4	78.6, 13.1	
			MEDIAN	260	308		221	278	
			MIN, MAX	175, 373	234, 573		132, 354	117, 474	
			5%, 95%	186.0, 363.0	245.0, 550.0		150.0, 302.0	166.0, 434.0	
	Week 3		N	30	37	0.1615	31	36	0.0160
			MEAN, GEO MEAN	271, 261	306, 291		226, 216	275, 262	
			SD, SE	72.6, 13.3	102.8, 16.9		62.4, 11.2	85.9, 14.3	
			MEDIAN	269	300		234	273	
			MIN, MAX	121, 465	144, 634		111, 354	111, 509	
			5%, 95%	155.0, 383.0	148.0, 573.0		116.0, 328.0	153.0, 449.0	
	Week 6		N	30	36	0.0008	30	35	0.0014
			MEAN, GEO MEAN	242, 236	312, 300		226, 220	276, 268	
			SD, SE	54.7, 10.0	84.7, 14.1		49.8, 9.1	64.5, 10.9	
			MEDIAN	244	302		225	279	
			MIN, MAX	157, 394	153, 483		123, 335	124, 394	
			5%, 95%	166.0, 329.0	191.0, 458.0		133.0, 293.0	160.0, 394.0	
	Overall		N	90	112	0.0000	93	107	0.0000
			MEAN, GEO MEAN	258, 251	316, 304		227, 220	278, 267	
			SD, SE	59.9, 6.3	87.8, 8.3		54.8, 5.7	76.3, 7.4	
			MEDIAN	254	306		229	274	
			MIN, MAX	121, 465	144, 634		111, 354	111, 509	
			5%, 95%	168.0, 363.0	191.0, 483.0		132.0, 322.0	160.0, 405.0	

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Source: <https://www.industrydocuments.ucsf.edu/docs/yrcj0001>

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TABLE 14.2.1-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
(Page 4 of 7)

Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value*
C-Reactive Protein (mg/dL)	Week 1	N	62	66	66	0.0166
		MEAN, GEO MEAN	0.384, 0.208	0.308, 0.131	0.308, 0.131	
		SD, SE	0.4771, 0.0606	0.7115, 0.0876	0.7115, 0.0876	
		MEDIAN	0.199	0.126	0.126	
		MIN, MAX	0.021, 2.790	0.020, 5.500	0.020, 5.500	
	Week 3	5%, 95%	0.0, 1.3	0.0, 0.9	0.0, 0.9	
		N	63	65	65	0.0111
		MEAN, GEO MEAN	0.370, 0.193	0.225, 0.117	0.225, 0.117	
		SD, SE	0.4639, 0.0584	0.3594, 0.0446	0.3594, 0.0446	
		MEDIAN	0.218	0.108	0.108	
	Week 6	MIN, MAX	0.023, 1.900	0.022, 2.200	0.022, 2.200	
		5%, 95%	0.0, 1.5	0.0, 0.9	0.0, 0.9	
		N	63	65	65	0.0335
		MEAN, GEO MEAN	0.373, 0.196	0.323, 0.131	0.323, 0.131	
		SD, SE	0.4707, 0.0593	0.6399, 0.0794	0.6399, 0.0794	
	Overall	MEDIAN	0.213	0.116	0.116	
		MIN, MAX	0.022, 2.480	0.020, 3.560	0.020, 3.560	
		5%, 95%	0.0, 1.2	0.0, 1.6	0.0, 1.6	
		N	188	196	196	0.0000
		MEAN, GEO MEAN	0.375, 0.199	0.285, 0.126	0.285, 0.126	

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TABLE 14.2.3-1
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL
(Page 4 of 7)

Biomarker	(mg/dL)	Timepoint	Statistic	Smokers			Non-Smokers		
				Male	Female	P-value*	Male	Female	P-value*
C-Reactive Protein	Week 1		N	26	36	0.0060	31	35	0.0006
			MEAN, GEO MEAN	0.223, 0.130	0.500, 0.293		0.146, 0.079	0.451, 0.206	
			SD, SE	0.3022, 0.0593	0.5462, 0.0910		0.2579, 0.0463	0.9296, 0.1571	
			MEDIAN	0.120	0.304		0.071	0.172	
			MIN, MAX	0.021, 1.530	0.022, 2.790		0.020, 1.330	0.028, 5.500	
	Week 3		5%, 95%	0.0, 0.5	0.0, 1.4		0.0, 0.7	0.0, 1.4	
			N	26	37	0.1990	31	34	0.0001
			MEAN, GEO MEAN	0.339, 0.156	0.391, 0.225		0.088, 0.068	0.349, 0.192	
			SD, SE	0.5218, 0.1023	0.4248, 0.0698		0.0781, 0.0140	0.4599, 0.0789	
			MEDIAN	0.149	0.259		0.059	0.147	
Cholesterol	Week 6		MIN, MAX	0.023, 1.900	0.027, 1.630		0.022, 0.425	0.027, 2.200	
			5%, 95%	0.0, 1.7	0.0, 1.5		0.0, 0.2	0.0, 1.5	
			N	27	36	0.0172	29	36	0.0027
			MEAN, GEO MEAN	0.278, 0.135	0.445, 0.259		0.256, 0.086	0.377, 0.185	
			SD, SE	0.4324, 0.0832	0.4912, 0.0819		0.6543, 0.1215	0.6320, 0.1053	
	Overall		MEDIAN	0.157	0.329		0.065	0.164	
			MIN, MAX	0.022, 1.940	0.032, 2.480		0.020, 2.980	0.026, 3.560	
			5%, 95%	0.0, 1.2	0.0, 1.5		0.0, 2.2	0.0, 1.6	
			N	79	109	0.0002	91	105	0.0000
			MEAN, GEO MEAN	0.280, 0.140	0.445, 0.257		0.161, 0.077	0.393, 0.194	